



## ATTACHMENT B

### REMARKS

By the present amendment, minor changes have been made to the claims without affecting their scope. For reasons as stated below and in the attached declaration, the invention as presently claimed is not disclosed or suggested in the prior art cited by the Examiner, and withdrawal of the rejections and allowance of the claims in their present form is respectfully requested.

In the present amendment, the one independent claim of the patent, Claim 16, has been amended in such a way as to further emphasize the substantial differences between the present claims and the cited prior art. In particular, as set forth in the specification of the present application, the liquid test specimen or sample is directed through openings 51 in the test card at the location wherein it will directly contact the sample receiving portion of the test strip. Despite the Examiner's comments at pages 2-3 of the most recent action with regard to what the present specification does or does not include, there is no question that the present specification specifically discloses such a structure.

In particular, the embodiment as shown in Fig. 9 and as described at pages 11-12 of the specification quite clearly discloses a test card wherein "the test strips are covered but the pertinent test and sample [receiving] portions of the test strips are exposed through openings." See specification at Page 11, lines 17-20. The specification at Page 12, top paragraph, then goes on to describe the test window openings or windows 50, as well as sample openings 51 through which the specimen to be tested passes so as to directly contact the front surface of the sample receiving

portion. As specifically stated in the specification, "At the lower end of the card are **provided sample openings 51 through which the liquid test specimen is able to contact the absorbent or sample portions of the test strips.**" See Page 12, lines 7-9.

Accordingly, the specification and drawings clearly and unambiguously disclose a test card which has openings for the testing portion and the sample receiving portion, and clearly and unambiguously show that the test card of this embodiment is designed so that the sample directly contacts the test strip through the opening that is located right over the sample receiving portion of the test strip. In this regard, the present amendments are fully supported by the specification and drawings, and no new matter has been entered.

In the Official Action, Claims 16 and 19 were rejected under 35 U.S.C. Section 103 as being unpatentable over May et al. publication WO 88/08534 in view of Sun et al. U.S. Patent 5,238,652, and Claims 16-19 were rejected under 35 U.S.C. Section 103 as being unpatentable over May et al. publication WO 88/08534 in view of Sun et al. U.S. Patent 5,238,652, and further in view of Boger et al. U.S. Patent 4,518,565. These rejections, insofar as applied to the claims as amended, are respectfully traversed.

As indicated above, the invention as presently claimed comprises an improvement in drug test immunoassays in that an extremely quick and accurate test of a drug of abuse may be obtained in a simple and effective manner. As reflected in the present claims, in the present invention, the test card is designed with openings directly over the sample receiving portion so that the liquid specimen sample can directly impinge the test strip on its front surface so as to begin instantaneously the capillary action needed to bring the sample through the test portion. For this reason, the drug

test card of the present invention obtains accurate readings of drugs of abuse in a rapid manner that is far different than the manner accomplished by the prior art cited by the Examiner.

In particular, the device as disclosed in the cited May et al. PCT publication does **not** disclose or suggest the present claims, and instead this reference teaches a device where the sample is only indirectly applied to a sample receiving portion on the front surface of the test strip. Indeed, as shown in each and every embodiment of May, e.g., Figs. 5 through 14, May teaches that the fluid sample will only **indirectly** reach a sample receiving portion on the front surface of a test strip. For example, while the embodiment in Figs. 11-12 contains an opening at the lower end of the device, aperture 601, through which a sample may pass through, the aperture 601 is **not directly over test strip 606**, and thus the device **precludes** the possibility that the sample will directly contact the front surface of the test strip. In fact, the embodiment at Figs 11-12 includes a porous receiving member 605 into which the sample is placed, and it is only through this indirect means that the sample will ultimately contact test strip 606.

Even further, the May patent teaches that a thermoplastic backing sheet 607 is in firm contact with the inner surface 608 of casing 600, and “provides a **seal against apertures 603 and 604 to prevent ingress of moisture or sample into the casing.**” See May PCT at Page 27, lines 27-31. The device of May once again **precludes** direct contact of the fluid sample onto the front surface of the test strip, and even provides a seal to ensure that this **does not** happen. The May PCT publication clearly **teaches away** from the present claims, and clearly does not disclose or suggest the presently claimed invention.

The other references cited by the Examiner, namely the Sun US patent 5,238,652 and the Boger US Patent 4,518,565, also do not disclose or suggest an immunoassay test card wherein openings are provided so that the liquid specimen can be directly contacted with the front surface of the sample receiving portion of a test strip, and thus these references are not relevant and cannot be combined with the May PCT publication to make the present claims obvious. Accordingly, the present claims are clearly patentable over the cited references, and the rejections should be withdrawn on this basis alone.

However, it is even further the case that there are secondary considerations present with regard to the claimed invention that further underscore the non-obviousness of the invention. In particular, the products which have embodied the claimed invention have had great commercial success, with products sales of over \$60 million dollars since the entry of the device into the marketplace a few years ago. See attached Declaration under 37 C.F.R. §1.132 of Keith Palmer<sup>1</sup>. It is well established that evidence of secondary considerations such as commercial success **must** be considered as evidence of non-obviousness, see, e.g., Fromson v. Advance Offset Plate, Inc., 225 USPQ 26 (Fed. Cir. 1985) and Hughes Aircraft Co. v. U.S., 8 U.S.P.Q.2d 1580 (U.S. Claims Ct. 1988). Indeed, on many occasions, commercial success has been held to be the most determinative factor in a finding of non-obviousness, see, e.g., Simmons Fastener Corp. v. Illinois Tool Works, Inc., 222 USPQ 744 (Fed. Cir. 1984), where the Court cited In re Mageli, 176 USPQ 305, 307 (CCPA 1973) for the proposition that "Indeed, *evidence of secondary considerations may often*

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<sup>1</sup> An executed copy of this document will follow shortly.

*be the most probative and cogent evidence in the record. It may often establish that an invention appearing to have been obvious in light of the prior art was not.” (emphasis in original).*

Thus, in addition to the foregoing showing that the May PCT publication does **not** disclose or suggest the invention as presently claimed, and indeed **teaches away** from that invention because it **precludes** the direct contact of the sample onto the front surface of the test strip at the sample receiving portion, the substantial commercial success of the test cards in accordance with the present invention only further evidences its non-obviousness over the cited prior art.

Accordingly, the Examiner's rejections of the claims on the basis of the cited prior art references, insofar as applied to the claims as amended, are respectfully traversed and should be withdrawn.

In light of the amendments and arguments as set forth above, and the attachments hereto, Applicants respectfully submit the present application has been placed in condition for allowance, and such action is earnestly solicited.

**END OF REMARKS**